Approved by Bath Clinical Area Partnership
Prescribing & Therapeutics Committee May 2016

NHS Bristol CCG
NHS North Somerset CCG
NHS South Gloucestershire CCG
North Bristol NHS Trust
University Hospitals Bristol NHS Foundation Trust
Weston Area Health NHS Trust

BNSSG Shared Care Guidance

Section 1: Heading

Drug	Sevelamer
Amber ***one month***	
Indication	Hyperphosphataemia in adult patients with chronic kidney disease
Speciality / Department	Renal and Transplant Directorate
Trust(s)	North Bristol NHS Trust

Section 2: Treatment Schedule

Usual dose and frequency of administration	Usual starting dose for adults over 18 years is 2.4-4.8g daily, in divided doses, taken with meals. The dose is then adjusted according to serum phosphate level. The usual dose range is 2.4 to 12g daily. Given that sevelamer reduces gastrointestinal phosphate absorption from food, tablets should be taken with meals.
Route and formulation	800mg sevelamer hydrochloride oral tablets 800mg sevelamer carbonate oral tablets 2.4g sevelamer carbonate oral powder
Duration of treatment	Ongoing

Section 3: Monitoring

Please give details of any tests that are required before or during treatment, including frequency, responsibilities (please state whether they will be undertaken in primary or secondary care), cause for adjustment and when it is required to refer back to the specialist.

Baseline tests - where appropriate
No specific monitoring in primary care is required. All monitoring of serum phosphate, calcium and parathyroid hormone levels will be performed by the hospital/dialysis unit and dose adjustments made accordingly by doctors or dieticians in conjunction with primary care.
Subsequent tests - where appropriate
1. N/a

Section 4: Side Effects

Side effects and management	As sevelamer itself is not absorbed, the most common side effects relate to local GI disturbance and include nausea, vomiting, diarrhoea, dyspepsia, flatulence, upper abdominal pain and constipation. Very rare cases of intestinal obstruction have been reported. Patients with renal insufficiency may develop hypocalcaemia or hypercalcaemia. Sevelamer does not contain calcium. If hypocalcaemia occurs, refer back to patient's consultant for advice.
Referral back to specialist	

Section 5: Drug Interactions

Please list clinically significant drug interactions (eMC link please click here)

Significant Drug Interactions	Sevelamer reduces the bioavailability of ciprofloxacin by approximately 50%; consequently it should not be taken simultaneously with ciprofloxacin. Very rare cases of increased TSH levels have been reported in patient's co-administered sevelamer and levothyroxine. Closer monitoring of thyroid function is therefore recommended in patients receiving both medicinal products. Patients taking anti-arrhythmic medications for the control of arrhythmias and anti-seizure medications for the control of seizure disorders were excluded from clinical trials. Caution should be exercised when prescribing sevelamer to these patients. When administering any medicinal product where a reduction in bioavailability could have a clinically significant effect on safety or efficacy, the medicinal product should be administered at least one hour before, or three hours after sevelamer, or the physician should consider monitoring blood levels.
Reminder to ask patient about specific problems	Patients who are constipated should be monitored carefully while being treated with sevelamer.

Section 6: Contra-indications, Cautions and Special Recommendations

Please list

Sevelamer should not be used in patients with gastrointestinal motility disorders and is contraindicated in hypophosphataemia or bowel obstruction. In very rare cases, intestinal obstruction and ileus/sub-ileus have been observed in patients during treatment with sevelamer, Constipation may be a preceding symptom. Patients who are constipated should be monitored carefully while being treated with sevelamer. Sevelamer treatment should be re-evaluated in patients who develop severe constipation or other gastro-intestinal symptoms. The safety of sevelamer has not been established in pregnant or lactating women. Sevelamer is available as two salts, hydrochloride and carbonate. The prescriber should take care to consistently prescribe the same salt.

Section 7: Advice to the patient

Advice for prescribing clinician to inform patient

1. Patient should take sevelamer with meals and adhere to their prescribed diet. The tablets should be swallowed whole and not chewed.

Section 8: Responsibilities for Secondary Care

Core responsibilities

1. Initiating treatment and prescribing for the first month
2. Undertaking the clinical assessment and monitoring for the duration of treatment.
3. Communicate details of the above in 1 and 2 to GP within the first month of treatment. This information should be transferred in a timely manner.
4. Refer patients to GP and provide information of further action where appropriate e.g. blood test is due.
5. To provide advice to primary care when appropriate.
6. Review concurrent medications for potential interaction prior to initiation of sevelamer.
7. Stopping treatment where appropriate or providing advice on when to stop.
8. Reporting adverse events to the MHRA.
9. Reminder to ask patients about particular problems see section 5.

Other specific to drug

1. Undertaking the clinical assessment and monitoring for the duration of treatment

Section 9: Responsibilities for Primary Care

Core responsibilities

1. Responsible for taking over prescribing after the first month
2. Review of any new concurrent medications for potential interactions.
3. Reporting adverse events to the MHRA.
4. Refer for advice to specialist where appropriate.
5. Reminder to ask patients about particular problems see section 5.

Other specific to drug

1. Secondary care will continue to undertake all monitoring for the duration of treatment.

Section 10: Contact Details

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Section 11: Document Details

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Section 12: Collaboration

Specialists in any one discipline are encouraged to collaborate across the health community in preparing shared care guidance. Please give details

1.

Section 13: References

Please list references

1. Summary of Product Characteristics (SPC) for Renagel (sevelamer hydrochloride) accessed via www.emc.medicines.org.uk (last updated Nov 2014)
2. Summary of Product Characteristics (SPC) for Renvela (sevelamer carbonate) accessed via www.emc.medicines.org.uk (last updated March 2014)
3. Summary of Product Characteristics (SPC) for Sevelamer Carbonate Zentiva accessed via www.emc.medicines.org.uk (last updated Jan 2015)